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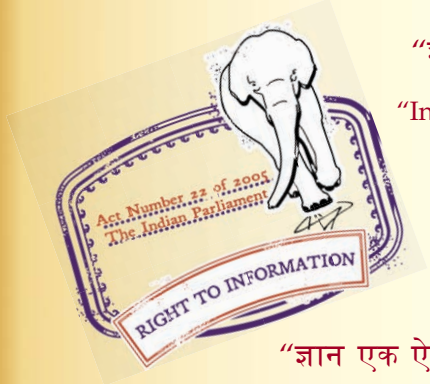
IS 8048 (1985): Electrocardiograph [MHD 19: Immuno-Biological Diagnostic Kits]



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IS : 8048 - 1985

Indian Standard

SPECIFICATION FOR ELECTROCARDIOGRAPH

(First Revision)

U.D.C. 616-12-008-3-073.96 : 615 : 845

INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr 8 *October* 1986

AMENDMENT NO. 2 SEPTEMBER 1994
TO
IS 8048 : 1985 SPECIFICATION FOR ELECTROCARDIOGRAPH .

(First Revision)

(*Page* 13, *clause* **8.8.2**) — Add the following note after this clause:

'NOTE — Class P electrocardiographs are little portable equipment and Class S electrocardiographs are more sophisticated (mostly stationary) equipment '

(MHD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 1 MARCH 1993
TO
IS 8048 : 1985 SPECIFICATION FOR ELECTROCARDIOGRAPH

(First Revision)

(*Page* 11, *clause* **8.5**, *line* 3) — Substitute 'preset' *for* 'present'.

(*Page* 12, *clause* **8.8.1**) — Substitute the following for the existing clause:

'The amplitude-frequency characteristic of the electrocardiographs shall be in the shaded area between the +0·83 dB line and the drawn line (*see* Fig. 3).'

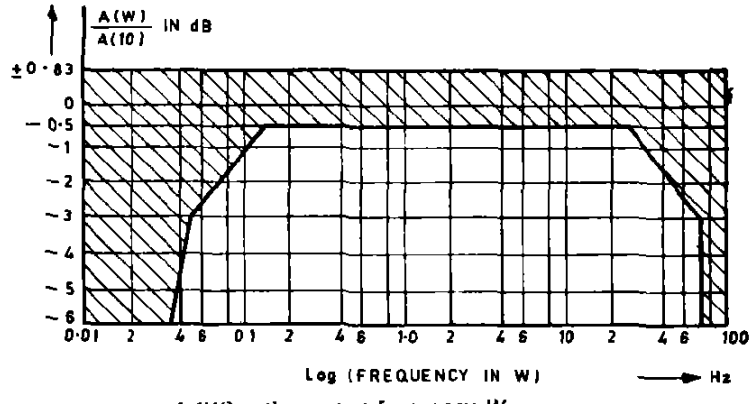
(*Page* 13, *Fig.* 2A) — Substitute the following caption of Fig. 2A for the existing caption:

'2B Application of Test Voltage to Bridged Patient Connections'.

(*Page* 13, *Fig.* 2B) — Substitute the following caption of Fig. 2B for the existing caption:

'2A Application of Test Voltage to Individual Patient Connections'.

(*Page* 14, *Fig.* 3) — Substitute the following figure for the existing figure:



A (*W*) is the gain at frequency *W*

A(10) is the gain at 10 *Hz*

FIG. 3 AMPLITUDE FREQUENCY CHARACTERISTICS

(*Page* 14, *clause* **8.10**) — Substitute the following for the existing heading:

'**Supply Frequency Interference**'

[*Page* 20, *clause* **10.1**(j)] — Substitute '(b) to (g)' *for* '(a) to (g)'.

[*Page* 21, *clause* **10.6**(c)] — Substitute 'col 4' *for* 'col 3'.

(MHD 19)

Printed at Printwell Printers, Aligarh, India

Indian Standard

SPECIFICATION FOR ELECTROCARDIOGRAPH

(First Revision)

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Indian Standard

SPECIFICATION FOR ELECTROCARDIOGRAPH

(First Revision)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 21 August 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council

0.2 This Indian Standard was first published in 1976 and has been revised to incorporate latest development.

0.3 Methods for using electrocardiographs are not covered in this standard but some essential information relating to use of electrocardiographs is given in Appendix A

0.4 Appendix B describes a simple device by which some of the more important performance requirements, like low and high frequency response, linearity, input impedance and common mode rejection ratio may be spot checked.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

---

1. SCOPE

1.1 This standard covers the safety and performance requirements and test methods for direct-writing single-channel and multi-channel electrocardiographs.

*Rules for rounding off numerical values (*revised*).

1.1.1 It also includes the requirements for recording chart.

1.2 This standard does not cover electrocardiograph for direct recording from heart muscles.

2. TERMINOLOGY

2.0 For the purpose of this s andard, the following definitions shall apply.

2.1 **Accuracy** — The deviation of result obtained by a particular method from the true value. It is usually expressed as a percentage of full scale.

2.2 **Common Mode Rejection** — The ability of a differential amplifier to reject common mode signals It is expressed as a ratio, namely,

$$\text{Common mode rejection ratio (CMRR)} = \frac{\text{Gain of amplifier to differential mode signal}}{\text{Gain of amplifier to common mode signal}}$$

2.3 **Direct-Writing Electrocardiograph** — An item of electromedical equipment in which electrodes are directly applied to a patient externally for the purpose of recording on paper the fluctuating voltages caused by the heart's action

NOTE — Direct-writing electrocardiographs are hereinafter referred to as 'Electrocardiographs' throughout this specification

2.3.1 *Single-channel Electrocardiograph* — Equipment for the recording of one electrocardiograph only.

2.3.2 *Multi-channel Electrocardiograph* - Equipment for the simultaneous recording of several electrocardiographs, often combined with phonocardiography and pulse recording.

2.4 **Distortion** — The change in shape of an electrocardiographic waveform introduced by the recording instrument.

2.4.1 *Linear Distortion* — A type of distortion resulting when, for a sinusoidal input, the gain of instrument varies with the frequency of the sinusoidal signal.

2.4.2 *Non-linear Distortion* — A type of distortion in which the output departs from a sinusoidal wave shape when the input is sinusoidal.

2.5 **Frequency Response** — A record of the sensitivity of the electrocardiograph *versus* frequency of sinusoidal input in the specified range keeping input constant.

2.6 **Impedance** — A measure of the opposition to flow of an alternating current in a circuit and caused by the combination of resistance,

capacitive reactance and inductive reactance. It is the ratio of the effective voltage to the effective current.

2.7 Input Signal — The signal injected into the electrocardiograph.

2.8 Input Terminal — The terminal or terminals for the input signal of an electrocardiograph.

2.9 Input Circuit — The part of the electronic circuit immediately adjacent to the input terminals.

2.10 Linearity — A measure of the non-linear distortion (*see* **2.4.2**) in an electrocardiograph

2.11 Noise — Unwanted signal introduced either from the electrocardiograph or from other sources.

2.12 Output — The conversion of an input signal as it appears in the form of power, energy or signal from the electrocardiograph amplifier or as it appears in the form of recording on the electrocardiograph chart.

2.13 Output Terminal — The terminals or terminal of an amplifier to which the galvanometer is connected.

2.14 Output Circuit — That part of the electronic circuit immediately adjacent to the output terminals.

2.15 Sensitivity — The amplitude of the output produced by a given input voltage expressed in mm/mV.

2.15.1 *Standard Sensitivity* — A sensitivity of 10 mm/mV.

2.16 Signal — The electrocardiographic waveform attributable to the electrical activity of the myocardium.

2.17 Skew — The departure of the writing stylus from an absolutely vertical path, that is, from a path perpendicular to the direction of movement of the paper.

2.18 Time Constant — The time required for the recorded output obtained from a direct current step input to decay to 36 8 percent of its original magnitude.

2.19 Lead Electrode — Electrode fastened on a certain part of the body to detect heart action potentials in combination with another electrode.

2.20 Neutral Electrode — Reference point for differential amplifiers and or connection for an ac suppressor amplifier involved in electrocardiograph lead combinations.

2.21 Central Terminal According to Wilson — Terminal with average potentials of the right arm, left arm and left leg potentials.

2.22 Central Point According to Goldberger — A point with average potentials of 2 limbs.

2.23 General — Comprises recording system with the proportionate width of the recording paper and the associated amplifier.

2.24 Type Tests — Tests carried out to prove conformity with the requirements of this standard. These are intended to prove the general qualities and design of a given type of equipment.

2.25 Acceptance Tests — Tests carried out on samples taken from a lot for the purpose of acceptances of the lot.

2.26 Routine Tests — Tests carried out on each item to check the essential requirements which are likely to vary during production.

3. SERVICE CONDITIONS

3.1 Electrocardiographs shall be capable of complying with the requirements of this specification over the full range of each of the following conditions including any combinations thereof :

a) Over the temperature range 10 to 40°C inclusive,

NOTE — The electrocardiograph shall be able to withstand a temperature of 40 to 50°C in dry heat condition.

b) At altitudes from sea level to 3 000 m above sea level,

c) At relative humidities up to 95 percent inclusive, and

d) 1) For electrocardiographs operating from a nominal 240 V, 50 Hz supply — at any supply voltage within the range 200-255 V inclusive and 48-52 Hz inclusive.

2) For battery-operated electrocardiographs — to the end point of the voltage limits specified by the manufacturer.

4. CONSTRUCTION AND GENERAL REQUIREMENTS

4.1 General — All the sub-systems shall be fully transistorized. Electrocardiograph shall be so designed and constructed that it meets the safety and performance requirements It shall be finished externally to withstand the normal handling. Attention shall be given to the layout of the controls and their labelling to provide effortless operation over long period with minimum error. The grouping of controls and the type of knobs used should be such that they can be operated by touch without the removal of the attention of the recordist from the patient or the

record. Construction should also be made such that the view of the patient is not obstructed by any portion of the equipment.

4.2 Nature of Supply — The system shall be designed to work from supply mains and/or battery.

4.3 Electrocardiograph Amplifier

4.3.1 The amplifier shall be capable of amplifying the cardiac signals from the patient and displaying diagnostic quality electrocardiograph on the pen recorder. It shall be completely transistorized. The amplifier shall have a differential input.

4.3.2 Sensitivity shall be such as to give a deflection of not less than 15 mm for an input of 1 mV. The sensitivity shall be adjustable.

4.4 Electrocardiograph Electrodes

4.4.1 The electrocardiograph electrodes shall be light-weight and comfortable for the patient to wear.

4.4.2 The electrodes shall be made of suitable non-corrodable material.

4.4.3 The electrode-cable shall be connected to the electrocardiograph machine through a suitable plug.

4.5 Recorder

4.5.1 This is meant for obtaining a permanent record of the electrocardiograph on paper. The recorder shall comply with the requirements specified in **4.5.2** and **4.5.3**.

4.5.2 The graduated portion of the chart shall be at least 40 mm in width, the overall width shall be +50 mm maximum.

4.5.3 Recording shall be permanent.

4.6 Control and Functions

4.6.1 In integrated electrocardiographs, the following controls and functions shall be present:

a) Power OFF, ON, CHART movement switch;

b) 1 mV switch for calibration;

c) Socket for electrode-cables;

d) Sensitivity control knob either preset or continuously variable;

e) Output terminal for electrocardiograph (optional);

f) Lead selector switch for leads I, II, III, *aVR*, *aVL*, *aVF*, *V* or V_1, V_2, V_3, V_4, V_5, V_6 and test position;

g) A trace reset facility;

h) A lamp or flag or indicator to indicate presence of power;

j) Stylus heat control and control knob, uncalibrated (in case of heat-sensitive writing system);

k) Stylus position control knob, uncalibrated;

m) Chart speed control switch, where possible;

n) Paper roll machinism;

p) Transparent cover on the stylus; and

q) Facility for recording any other phonomenon through input socket.

4.6.2 In multi-channel electrocardiographs the lead selector system shall at least enable sequential selection of test and lead positions I, II and III, *aVR*, *aVL* and *aVF* and V_1, V_2, V_3, V_4, V_5 and V_6.

5. GENERAL SAFETY REQUIREMENTS

5.1 Compliance with Other Requirements — The electrocardiograph shall comply with the relevant requirements specified in IS : 8607 (Part 1)-1977*.

6. PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

6.1 The relevant requirements of IS : 8607 (Part 2)-1978† shall apply.

6.2 Isolation from Supply Mains (Mains-Operated Electrocardiographs Only) — Electrocardiographs operating from the mains supply shall have all patient circuits effectively isolated from the mains supply by means of a transformers having the secondary winding insulated from the primary winding by means not inferior to those specified for protective isolating transformer specified in IS : 8607 (Part 7)-1985‡.

6.2.1 The transformer shall be capable of passing the relevant tests prescribed in **10.5**, **10.6**, **10.20** and **10.21**.

6.2.2 Conductors and components electrically connected to the patient circuit shall be:

a) double insulated, and

General and saftey requirements for electrical equipment used in medical practice:

*Part 1 General.

†Part 2 Protection against electric shock

‡Part 7 Construction.

b) arranged and supported so that in the event of a failure such as loosening of terminals for breaking of conductors they may not make electrical contact with live conductors components electrically connected to the primary winding of the transformer.

6.3 Cord Anchorages — The requirements specified in **20** of IS : 302-1977* shall apply.

6.4 Screws Threads and Fixing — The requirements specified in **23** of IS : 302-1977* shall apply.

7. MARKING IDENTIFICATION AND DOCUMENTS

7.1 Marking on the Outside of Equipment

7.1.1 In addition to the provisions of **7.1** to **7.2** of IS : 8607 (Part 1)-1977†, the requirements specified in **7.1.2** and **7.1.3** shall apply.

7.1.2 If applicable marking on the panel that the electrocardiographs is protected against the effects of defibrillation (*see* **8.7.2**).

7.1.3 *Instructions for Use* — The instructions for use shall additionally contain the following:

a) Advice on the procedures necessary for safe operation to avoid hazards, which may occur as a result of an inadequate electrical installation;

b) Advice that conductive parts of electrodes and their connectors, including the neutral electrode, should not contact other conductive parts including earth;

c) Advice on the type of electrical installation to which the equipment may be safely connected, including the connection of any potential equalization conductor;

d) The specification (or type-number) of the patient cable to meet any defibrillation protection and protection against high frequency burns (*see* **8.7.2**);

e) If the electrocardiograph is provided with protective means against burns when used with HF surgical equipment such means shall be described;

f) Advice on the possible hazard caused by the summation of leakage currents when several equipments are interconnected;

g) Instructions for regular testing of the electrocardiographs and the patient cable;

*General and safety requirements for household and similar electrical appliances (*fifth revision*).

†General and safety requirements for electrical equipment used in medical practice: Part 1 General.

h) Where relevant a statement that the electrocardiographs is protected against the effects of a cardiac defibrillator discharge; and

j) Advice on the precautions to be taken when a defibrillator is used on a patient.

8. PERFORMANCE REQUIREMENTS

8.1 Recording Co-ordinates and Pen Position

8.1.1 *Recording Co-ordinates* — Electrocardiographs shall be designed and constructed so as to record on rectilinear co-ordinates and not on curvillinear co-ordinates.

8.1.2 *Pen Position* — The pen position shall be variable over a width of 15 mm on both sides of the central line.

8.2 Linearity — When tested in accordance with the method indicated in **10.16**, electrocardiograph shall show amplitude up to 20 mm in upper and lower side and shall not permit over 10 percent +0·5 mm variation in upper and lower, 15 mm from base line illustrated in Fig. 1.

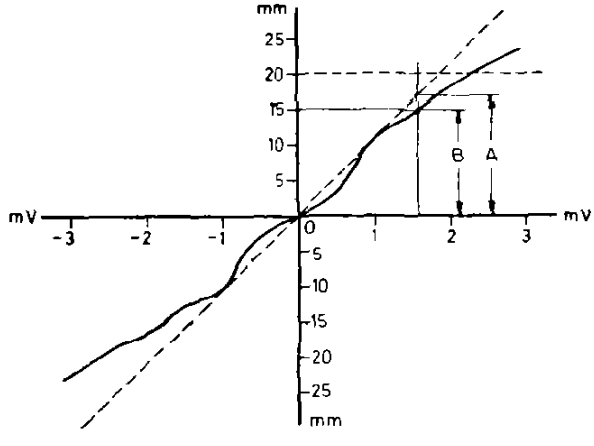


FIG. 1 BASE LINE FOR TESTING OF LINEARITY

8.3 Interlead and Input Impedance

8.3.1 *Interlead Impedance* — Interlead impedance shall be not less than 0·3 MΩ between any pair of active patient electrodes at any position of the lead selector in the frequency range of 0·1 to 200 Hz.

This value of 0·3 MΩ is only high enough if the impedance between two (sum) electrode-skin resistances is lower than 30 kΩ.

NOTE — The amplifier interlead impedance shall be sufficiently high to satisfy the requirement of **8.6.3**. When impedance is lower than 0 3 MΩ, it is possible that the electrocardiograph may be misinterpreted.

8.3.2 *Input Impedance* — The input impedance shall be not less than 2 × 2 MΩ in common mode and 4 MΩ in differential mode.

8.4 Limiting Value of dc Current — DC current in any input lead shall not exceed 0·1 μA.

8.5 Adjustment of Sensitivity — The sensitivity is to be adjustable from the panel of the instrument continuously by an uncalibrated knob or by a present sensitivity control knob, in which case the selectable ranges shall be 5 mm/1 mV, 10 mm/1 MV and 20 mm/1 mV.

8.6 Stability

8.6.1 *Fluctuation of Recording Base Line* — When tested in accordance with the method as indicated in **10.12.1**, single-channel electrocardiograph shall show less than ±1 mm aberration of base line in 20 seconds, and multi-channel electrocardiograph, less than ± 1 mm aberration of base line in 40 seconds.

8.6.2 *Fluctuation of Base Line Caused by Change of Power Source Voltage* — When the voltage of power source is charged for plus or minus 5 V according to the testing method indicated in **10.12.2**, ac-type electrocardiograph shall show less than ±5 mm deflection of base line in 20 seconds.

NOTE — The requirements for battery-operated electrocardiograph is under consideration.

8.6.3 *Variation of Recording Sensitivity* — When the voltage of power source is changed from 230 to 250 V according to the testing method indicated in **10.12.3**, ac-type electrocardiograph shall not permit more than ±10 percent change is recording sensitivity.

NOTE — The requirement for battery-operated electrocardiograph is under consideration.

8.7 Additional Requirements for Electrocardiographs to be Used with Pacemakers and Defibrillators

8.7.1 *Automatic Unblocking after Defibrillations* — An electrocardiograph shall be provided with means that a recorded electrocardiograph shall be visible within 5 seconds after a defibrillation pulse, at normal sensitivity of the electrocardiograph, 400 J or 4 000 V onto a 100 Ω or any equivalent pulse has been applied.

8.7.2 *Voltage withstand Test for Defibrillator-proof Equipment*

8.7.2.1 *General* — All equipment, which is marked as suitable for use with defibrillators, shall withstand the voltage withstand test specified in **8.7.2.2** to ensure:

a) that any accessible parts of equipment, patient cable connectors,

cables, etc, which are not connected to earth in normal use, will not become live due to flashover of defibrillator voltage; and

b) that the equipment will continue to function after exposure to defibrillator voltage.

NOTE — Patient-circuits can rise to high voltages when a defibrillator is in use, and accessible metal on connectors, cables, etc, carrying such patient-circuits must, therefore, be adequately earthed or adequately insulated from the patient-circuit.

This requirement applies to plug and socket combinations where the socket is chassis-mounted, and where the combination is used to connect parts of the patient cable, transducer lead, etc (for example, inline connectors).

The equipment shall be deemed to comply if:

a) during the test there is no failure or arcing over of insulation;

b) during the test, the accessible parts do not become live; and

c) after the test, the equipment is capable of correct operation.

8.7.2.2 *Test procedure and connections* — The equipment and test circuit shall be connected as described in Fig. 2A and then as described in Fig. 2B.

In the test described in Fig 2B, the test voltage is applied to all the patient-circuit connections bridged together and isolated from earth.

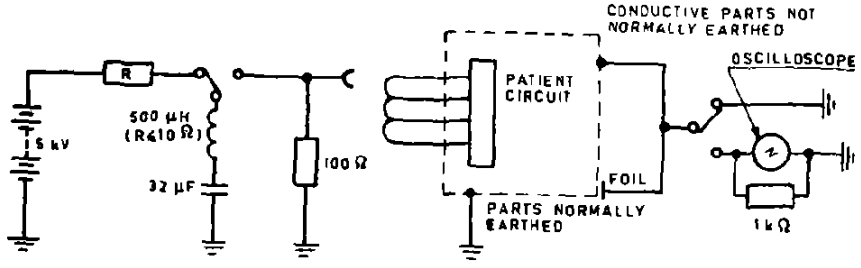
The accessible parts are first connected directly to earth to determine any flashover or insulation failure and then connected through an oscilloscope to earth to determine whether any part becomes live.

8.7.3 *Use with Pacemakers* — The function of an electrocardiograph shall not be affected unduly by operation of a pacemaker. Pacemaker and electrocardiograph waveforms should be visible on the recording.

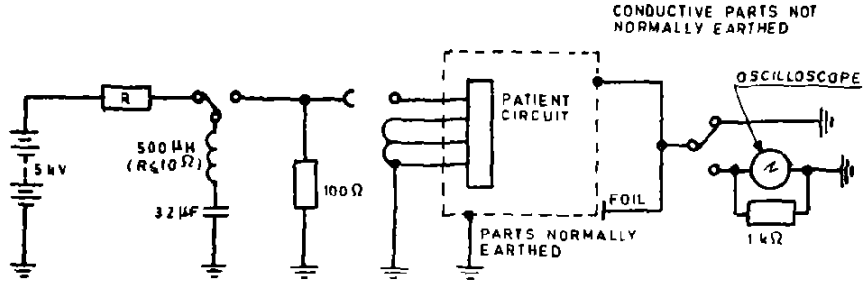
8.7.3.1 When pulses having an amplitude of 250 mV peak with a rise time of 10 microseconds and duration 1 millisecond and 100 pulses/minute are applied to the input of the electrocardiograph, which is set to 10 mm/mV sensitivity, the maximum cumulative shift of the base line should not exceed 10 mm.

8.8 Distortion

8.8.1 *Amplitude-frequency Characteristic* — Both Class P and Class S electrocardiographs shall have an amplitude-frequency characteristic in the shaded area between the +0·83 dB line and the drawn line (*see* Fig. 3).



2A Application of Test Voltage to Individual Patient Connections



2B *Application of Test Voltage to Bridged Patient Connections*

NOTE — *R* is included to protect contactor in test set-up.

FIG. 2 VOLTAGE WITHSTAND TEST ARRANGEMENTS

8.8.2 *Phase-frequency Characteristic* — Class S electrocardiographs shall not exceed maximum delay time difference between any two frequency in the range of 3 to 100 Hz of 4 milliseconds.

8.8.3 Maximum single overshoot shall be 10 percent for a square waveform, when step of 1 mV input is applied.

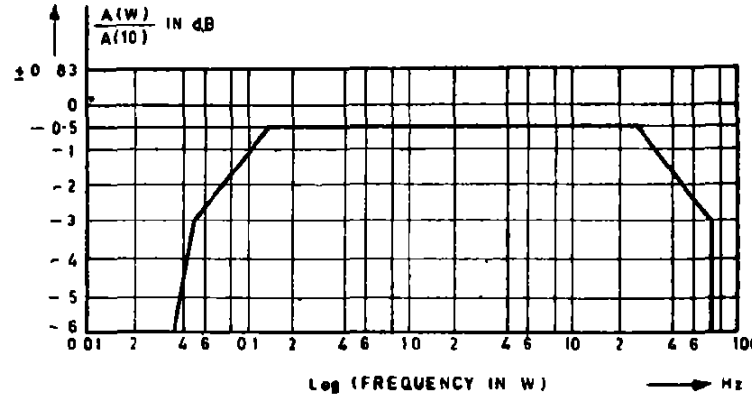
NOTE — This performance may be adversely affected if recording paper having a specification other than that recommended by the manufacturer is used.

8.8.4 *Time Constant* — Time constant shall be between 3 and 4 seconds, both inclusive. It is allowable to have 2 time constants (switchable) and, where a switch for lower time constant is applied, the shorter value should be 1·5 seconds minimum.

8.8.5 *Filter* — If a filter is used, it is recommended to have low-pass filter of −3 dB at 25 Hz (the slope of the filter shall not exceed 6 dB/octave).

NOTE — The effect of transients on the mains supply are under consideration.

8.9 Radio-Frequency Interference — The instrument shall be insensitive to interference caused by radio frequency sources, such as therapeutic and surgical diathermy equipment.



A (W) is the gain at frequency *W*.
A (10) is the gain at 10 *Hz*.

FIG. 3 AMPLITUDE FREQUENCY CHARACTERISTICS

8.10 Radio Frequency Interference — As a facility for reducing interference from supply mains, the electrocardiograph may be provided with a separate earthing terminal for connection to metal objects in the vicinity of a patient.

Such an earth terminal shall conform to relevant requirements of IS : 302-1979*.

8.11 Calibration

8.11.1 Signal of 1 mV shall be provided and it shall be possible to inject this signal into the amplifier for any lead position while the recording is in progress.

8.11.2 Means shall be provided for the calibration voltage to be:

a) added to the electrocardiogram and applied at the input of the amplifier from any lead position, and

*General and safety requirements for household and similar electrical appliances (*fifth revision*).

b) recorded with the patient disconnected from the instrument.

With multi-channel electrocardiographs, means shall be provided for the simultaneous application of the calibration signal to all channels.

8.12 Speed and Speed Accuracy — A minimum of two speeds, namely, 25 mm/s and 50 mm/s shall be available. The speed shall have an accuracy within ±3 percent when operating from a 50 Hz source.

NOTE 1 — Appropriate allowance shall be made if the frequency is different from 50 Hz.

NOTE 2 — The requirement for battery-operated electrocardiograph is under consideration.

8.13 Recording Chart — Electrocardiographs shall be supplied with recording chart having rectilinear rulings of 1·0 mm ± 1 percent pitch along both the time and voltage axes. Every fifth division shall be ruled darker than the others.

It is recommended that the ruled divisions cover a width not less than 40 mm.

The chart shall be capable of retaining its dimensional accuracies thoughout a temperature range of 10 to 50°C inclusive and for relative humidities from 10 to 95 percent inclusive.

It is recommended that the chart does not readily take finger marking or water marking.

8.14 Skew

8.14.1 *General* — Skew of recording, due to all causes, shall not exceed 0·1 mm of horizontal displacement per 10 mm of vertical deflection.

8.14.2 *Multichannel Electrocardiographs* — With the amplifiers for each channel set to the same frequency response limits, all traces shall fall dynamically within a 0·5 mm band of the ideal (zero skew) response at all transport speeds for the entire frequency range of the electrocardiograph.

NOTE — In multichannel recording it is especially important to ensure temporal alignment of traces.

8.15 Resolution of Recording — The vertical width of the undeflected trace shall be capable of adjustment so that it does not exceed 1·0 mm at any chart speed.

The electrocardiograph shall, at any paper speed and sensivity, leave a visible continuous trace when recording a triangular waveform

having a peak-to-peak amplitude equal to full chart width and a frequency within the range of 0 to 12 Hz.

NOTE — This waveform is approximately equivalent to a succession of QRS complexes at normal writing speeds.

The writing system shall be such that, with a sensitivity of 10 mm/mV, a step change of 50 microvolt at the input shall be readable on the trace.

8.16 Trace Reset — A trace reset facility shall be incorporated to operate whenever a new lead is selected.

With 100 mV dc applied to the input terminals the trace reset facility shall be capable of returning the trace to within 1 mm of its initial position within 0·5 second when the lead selector is switched between any two lead positions.

8.17 Auxiliary Input and Output

8.17.1 An auxiliary input may be provided. This may be of a single-ended and/or double-ended type.

8.17.2 It is recommended that electrocardiographs be provided with a tip and sleeve, single-ended jack to which the output of the instrument shall be wired such that the active electrode is connected to the tip.

The output signal, if provided, shall be direct coupled, shall have characteristics identical with those specified for the electrocardiograph and shall have a magnitude of 1 V per millivolt of electrocardiograph input. The signal shall be capable of driving a load of 10 kΩ or more and shall have an output impedance not exceeding 1 kΩ.

The signal at the jack shall be of such polarity that the tip is positive relative to the sleeve when the electrocardiograph is recording a signal which causes the pen to move upward on the chart.

The output signal shall have no dc offset voltage when the input is shorted.

The circuit of the auxiliary output shall be so designed and constructed that [illegible] deleterious effect results from short circuit. Additionally

that a peak change of ± 5 V rms in the supply voltage does not result in a deflection of the recorded output greater than 0·5 mm.

8.18.2 *Battery-Powered Electrocardiographs* — Battery-powered electrocardiographs shall be provided with a device to indicate when the battery voltage has fallen below the required minimum voltage specified by the manufacturer.

8.19 Patient Leads — Colour Coding and Marking of Terminals

8.19.1 The electrocardiograph shall have a connector with a free polarized socket coded to the various leads and which may not be inserted incorrectly.

8.19.2 Patient leads shall be of the appropriate colour specified in col 2 of Table 1. The patient terminals shall be legibly and indelibly marked with at least 4 mm long legend specified in col 3 of Table 1.

TABLE 1 PATIENT LEADS — COLOUR CODING AND MARKING OF TERMINALS

Lead	Colour	Patient Terminal Marking
(1)	(2)	(3)
Right arm	Red	*R*
Left arm	Yellow	*L*
Left leg	Green	*F*
Right leg	Black	*N*
Chest	White	*V* (in case of cardiograph with single chest lead) or V_1, V_2, V_3, V_4, V_5, V_6 in case of more than one chest lead

8.20 Patient Lead Configurations — The electrocardiographs shall be provided with bipolar lead configurations I, II and III and augmented unipolar lead configurations — *aVR*, *aV*, *aVF* and *V*, all of which shall be obtainable from lead selector. The configurations shall be in conformity with Fig. 4.

9. MARKING, INSTRUCTION FOR USE AND PROVISION OF CONTROL

9.1 Marking

9.1.1 Each electrocardiograph shall be marked indelibly and clearly with the following information:

a) Manufacturer's name or trade-mark;
b) Manufacturer's model, batch and serial number;
c) Single-channel or multi-channel;
d) Country of origin;

e) Mains- and battery-operated or only mains or battery operated;
f) Rated voltage;
g) Rated power; and
h) Symbol for defibrillator proof equipment [*see* **2.5.11** of IS : 2032 (Part 19)-1977*]

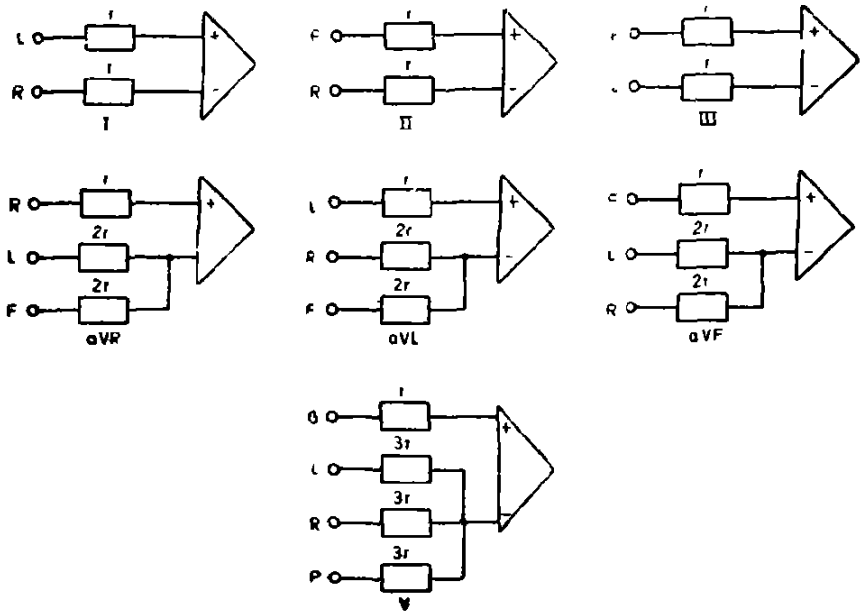


FIG. 4 LEAD CONFIGURATIONS

9.1.2 The electrocardiographs may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

9.2 Instruction for Use

9.3 Marking of Controls — The controls incorporated in the electrocardiograph shall be marked in accordance with Table 2.

*Graphical symbols used in electrotechnology: Part 19 Electrical equipment used in medical practice.

TABLE 2 MARKING OF CONTROLS

(*Clause* 9.3)

CONTROL	MARKING
(1)	(2)
Switch for switching electrocardiographs 'ON' and 'OFF'	'ON'
Control for selecting paper speed	(mm/s for example, 25 mm/s)
Calibration	1 mV
Lead selector	TEST/GAL, *I*, *II*, *III*, *aVR*, *aVL* *aVF*, *V* or V_1, V_2, V_3, V_4, V_5, V_6 (in case of more than one chest lead)
Positioning of trace	
Knob for varying sensitivity (continuous) OR Knob for varying sensitivity (preset)	5 mm/1 mV, 10 mm/1 mV, 20 mm/1 mV F
Switch for the high frequency cutout filter (if fitted)	
Stylus heat control	

10. TESTS

10.0 General — The electrocardiograph shall satisfactorily pass the tests prescribed in **10.1**, **10.2** and **10.3**.

NOTE 1 — Unless otherwise specified, the general test conditions shall be same as those specified in **3** of IS : 8607 (Part 1)-1977*.

NOTE 2 — Out of the tests specified in **10.1**, **10.2** and **10.3** the following shall be carried out both at the lower and higher end of the voltage range and at any frequency between 48 and 52 Hz:

a) Time constant,
b) Linearity,
c) Speed,
d) Sensitivity, and
e) 1 mV standardization.

*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

10.1 Type Tests — The tests specified in Table 3 shall constitute type tests. Three samples of the electrocardiograph of the same model, type and rating shall be subjected to these type tests. All the tests specified from Sl No. (iii) to (xxi) of Table 3 shall be carried out on the samples. On the third sample the following test shall be carried out in the order in which they are appearing below:

a) Dry heat,
b) Speed accuracy,
c) Sensitivity,
d) 1 mV standardization,
e) Overshoot,
f) Time constant,
g) Linearity,
h) Damp heat,
j) Tests specified under (a) to (g),
k) High voltage, and
m) Leakage current.

10.1.1 All samples shall successfully pass all the type tests for proving conformity with the requirements of this standard. If any of the sample fails in any of the type test, the testing authority, at its discretion, may call for fresh samples not exceeding twice the original number and subject them to all the tests or the tests in which failure(s) occurred. No single failure shall be permitted in the repeat test(s).

10.2 Acceptance Tests — The tests specified in Table 4 shall constitute acceptance tests.

10.2.1 A recommended sampling procedure for acceptance tests is given in Appendix C.

10.3 Routine Tests — The tests specified in Table 5 shall constitute routine tests.

10.4 Dry Heat Test — The test shall be carried out in accordance with IS : 9000 (Part 3/Sec 1 to 5)-1977*.

10.5 Damp Heat Test — The damp heat test shall be carried out in accordance with IS : 9000 (Part 5/Sec 1 and 2)-1981† for 1 cycle.

*Basic environmental testing procedures for electronic and electrical items: Part 3 Dry heat test, Section 1 to 5.

†Basic environmental testing procedures for electronic and electrical items: Part 5 Damp heat (cycling) test, Section 1 to 2.

TABLE 3 TYPE TESTS

(*Clause* 10 1)

Sl No.	Test	Clause Reference
(1)	(2)	(3)
i)	Dry heat	10.4
ii)	Damp heat	10.5
iii)	High voltage	10 6
iv)	Variation of mains voltage	10.7
v)	Cord anchorage	6.3
vi)	Screws, threads and fixing	6 4
vii)	Overload	10.8
viii)	Accuracy of the speed	10.9
ix)	Noise level	10.10
x)	Ability to withstand radio frequency interference	10.11
xi)	Stability	10.12
xii)	1 mV standardization	10.13
xiii)	Time constant	10.14
xiv)	Common mode rejection ratio	10.15
xv)	Linearity	10 16
xvi)	Distortion	10 17
xvii)	Damping/overshoot	10 18
xviii)	Filter	10.19
xix)	Voltage withstand test for defibrillator—proof equipment	8 7 2
xx)	Insulation resistance	10.20
xxi)	Leakage current	10.21
xxii)	Interlead and input impedance	10 22

10.6 High Voltage Test — Electrocardiographs shall be subjected to an ac voltage of :

a) 1 000 volts rms applied between the parts specified in **10.20**(a),
b) 1 000 volts rms applied between the parts specified in **10.20**(b), the patient electrodes being connected to earth;
c) the voltage specified in col 3 of Table 6 applied between the corresponding parts specified in col 1 of Table 2.

10.6.1 The voltage shall be applied in accordance with IS : 8607 (Part 2)-1978*.

*General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

TABLE 4 ACCEPTANCE TESTS

(*Clause* 10.2)

Sl No.	Test	Clause Reference
(1)	(2)	(3)
i)	High voltage	10.6
ii)	Overload	10.8
iii)	Accuracy of the speed	10.9
iv)	Noise level	10.10
v)	Stability	10.12
vi)	1 mV standardization	10.13
vii)	Time constant	10.14
viii)	Common mode rejection ratio	10.15
ix)	Linearity	10.16
x)	Distortion	10.17
xi)	Damping/overshoot	10.18
xii)	Insulation resistance	10.20
xiii)	Leakage current	10.21

TABLE 5 ROUTINE TESTS

(*Clause* 10.3)

Sl No.	Test	Clause Reference
(1)	(2)	(3)
i)	Stability	10.12
ii)	1 mV standardization	10.13
iii)	Time constant	10.14
iv)	Common mode rejection ratio	10.15
v)	Linearity	10.16
vi)	Distortion	10.17
vii)	Damping/overshoot	10.18
viii)	Insulation resistance	10.20
ix)	Leakage current	10.21

10.6.2 There shall be no failure or arcing over the insulation during any of the test, and immediately following the tests, insulation resistance test described in **10.20** shall be repeated.

TABLE 6 INSULATION RESISTANCE AND HIGH VOLTAGE TEST VALUES FOR DOUBLE INSULATED TRANSFORMER

(*Clause* 10.6)

Sl No.	Parts	Insulation Resistance	Voltage
(1)	(2)	(3)	(4)
		MΩ	kV (rms)
1.	Between input and output windings	100	3·5
2.	Between the input winding and core connected to any screen and any exposed conductive part	10	1
3.	Between the output winding and core connected to any screen and any exposed conductive part	10	1

10.7 Variation of Mains Voltage — The supply voltage shall be changed to ±5 percent of its peak value and the output shall be recorded. The deflection of the output due to this change of supply voltage shall not exceed 0·5 mm.

10.8 Overload — With the sensitivity control and lead selector switch at any position a voltage of 1·0 V rms shall be applied between any electrode and earth at any frequency within the range 48 to 52 Hz inclusive for not less than 2 seconds. Electrocardiographs shall be capable of withstanding this voltage without any deleterious effect.

10.9 Accuracy of the Speed — The mains operated electrocardiograph shall be supplied with a voltage from a 50 Hz source. The speed shall not deviate from the declared speed by more than ±3 percent.

NOTE — Test procedure for battery-operated electrocardiograph is under consideration.

10.10 Noise Level

10.10.1 *Random Noise* — With completely shielded 27 kΩ resistors connected from the right leg (*N*) electrode to each of the right arm (*R*), left arm (*L*), left leg (*F*) and chest (*V*) electrodes and sensitivity set at 10 mm/mV the output noise shall be measured. The noise shall not exceed the equivalent of 0 25 mm peak-to-peak on the chart for any position of the lead selector switch.

10.10.2 *Cross Talk Between Channels (Multi-channel Electrocardiographs Only)* — For multi-channel electrocardiograph the cross-talk between any two channels shall be measured and this cross-talk shall be better than 60 dB.

10.11 Ability to Withstand Ratio Frequency Interference — With the sensitivity set at 10 mm/mV, a 100 mV rms signal, 100 percent modulated at 50 Hz, at any frequency (carrier) between 0·25 and 35 MHz, applied between the reference (right leg) electrode and all other lead electrode connected together shall cause no perceptible deflection for the stylus for any position of the lead selector.

10.12 Stability

10.12.1 *Fluctuation of Recording Base Point* — The electrocardiograph fixed on a stable place and it is set in the standard sensitivity with 5 kΩ resistances connected to two inputs and groundings terminals of electrocardiograph. Then fluctuation of base line is measured for 20 seconds starting in five minutes after power source is switched on, in the case of single channel electrocardiograph. For multi-channel electrocardiograph the fluctuation of 40 seconds starting in ten minutes after power source is switched on is measured. The voltage of the power source shall not vary by more than 1 percent during the test.

10.12.2 *Fluctuation of Base Line Cause by a Change of Power Source Voltage* — The test is conducted by using a stable power source as prescribed in **10.12.1**. Single channel electrocardiograph and multi-channel prescribed electrocardiographs are connected to the supply for five minutes and ten minutes respectively before carrying out the test.

As indicated in Fig. 5 a series resistances, capable of giving to power source a potential difference of ±5 V over 240 V is inserted and the resistance is short-circuited or inserted by switching. The aberration of base line obtained within 20 seconds immediately following short-circuit or insertion shall be less than ±5 mm. A parallel condenser may be inserted to the switch for short-circuit.

NOTE — Test procedure for battery-operated electrocardiograph is under consideration.

10.12.3 *Variation of Recording Sensitivity* — The electrocardiograph is adjusted to standard sensitivity with stable power source of 240 ± 2 V. Then by continuously changing power source voltage from 230 to 250 V the recording sensitivity is checked. This sensitivity should remain within ±10 percent from that obtained with 240 ± 2 V power source.

NOTE — Test procedure for battery-operated electrocardiograph is under consideration.

10.13 Standardization — The calibration voltage shall be applied in such a manner as to determine the overall sensitivity of the amplifier attenuator and writing system. The calibrating voltage shall provide a pen displacement equal to that obtained from an input signal of 1 mV ± 5 percent applied at the electrode.

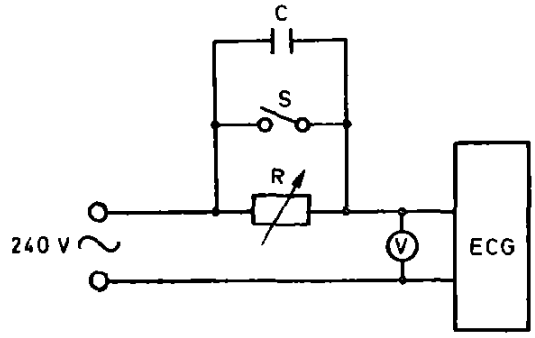


FIG. 5 MEASURING CIRCUIT FOR FLUCTUATION OF BASE LINE

10.14 Time Constant — Calibration signal of 1 mV is applied and the calibrator knob is kept pressed. The time, which the tracing takes to settle down to 36 8 percent of its original values, is measured. This measured time shall be between 3 and 4 seconds both inclusive.

10.15 Common Mode Rejection Ratio

10.15.1 The common mode rejection ratio shall be checked at differential offset voltages not exceeding 100 mV dc, and common mode offset voltage not exceeding 200 mV dc or 500 mV ac, applied to the input.

10.15.2 With electrocardiograph sensitivity set at 10 mm/mV and for each position of the lead selector switch, the deflection in the recorded output shall be measured with the following voltages applied between the right leg electrode and all other electrodes connected together.

a) 0·5 volt peak-to-peak at any frequency within the range 45 to 65 Hz inclusive (this corresponds to a common mode rejection ratio of 5 000 : 1); and

b) 50 mV peak-to-peak at any frequency outside the range 45 to 65 Hz inclusive (this corresponds to a common mode rejection ratio of 500 : 1).

The deflection shall not be more than 1·0 mm with or without the right leg electrode being separately connected to earth.

10.15.3 Electrocardiographs shall also pass the test specified in **10.15.2** when a resistance of 4·7 kΩ is placed in series with, and at the patient end of, any of the patient leads supplied with the equipment.

NOTE — To meet the above common mode rejection ratios, the patient cable screen may have to be driven with a signal equal to the common mode signal from the patient.

Furthermore, to meet the requirement when using augmented leads, a resistor which is equal in value to the equivalent resistance of averaging network may need to be inserted in series with the exploring electrode (that is, resistor r in Fig. 4).

If buffer amplifiers are used for each active electrode the values of resistor R may be reduced below that which would otherwise be necessary whilst still maintaining the requirements for common mode rejection and input impedance.

This note applies also to weighing networks other than the central terminal. For example, in a corrected orthogonal lead system, the value of the resistors chosen shall be sufficiently high to meet the input impedance specifications.

10.16 In Linearity — Test shall be conducted with electrocardiograph adjusted to standard sensitivity and by using step voltage generator for testing. By orderly increasing step input voltage at steps of 0·1 mV to positive and negative directions, the vertical deflection is noted. The vertical deflection of at least 20 mm should be obtainable. Also the variation of this deflection to base line is measured.

The variation to base line shall be calculated using the following equation and A and B in Fig. 1:

$$\text{Variation} = \frac{A - B}{A} \times 100 \text{ (percent)}$$

The base line shall be defined as a straight line that ties the starting point in non-input stage with the rising point at 10 mm.

10.17 Distortion

10.17.1 *Amplitude Frequency Characteristic* — The equipment shall be tested at nominal sensitivity, over the whole frequency band with a sinusoidal input signal of 1 mV.

10.17.2 *Phase-frequency Characteristic* — Test is under consideration.

10.18 Damping/Overshoot — Calibration signal of 1 mV is applied at standard sensitivity and the overshoot is measured on the trace. This over shoot shall not exceed 10 percent.

NOTE — Test for damping is under consideration.

10.19 Filter — The test on filter shall be carried out in the same manner as given in **10.17.1**.

10.20 Insulation Resistance (for Mains-operated Equipment Only) — The insulation resistance shall be measured at a voltage of 500 volts between the following:

a) Live supply terminals, and any exposed conductive parts and/or metal foil placed in intimate contact with non-conductive parts liable to be handled in service;

b) Live supply terminals, and all patient electrodes connected together; and

c) The parts of the double insulated transformer listed in col 1 of Table 6.

10.20.1 The insulation resistance so measured shall not be less than 2 MΩ for (a) above, 7 MΩ for (b) above, and the values given in col 2 of Table 6 for (c) above.

NOTE — Battery-*cum*-mains operated electrocardiographs (implying a built-in battery eliminator) shall be treated as mains-operated electrocardiograph.

In case of only battery-operated electrocardiographs, the manufacturer shall clearly indicate that it should be operated only from a battery source and not from any battery eliminator supplied from mains, as such operation may result in sub-standard performance and may not meet the safety requirements.

The manufacturer may opt to supply/suggest a suitable eliminator for battery operated electrocardiographs and, in such cases also, the battery operated electrocardiographs operated/intended to be operated from supplied/suggested battery eliminators shall be treated as mains-operated electrocardiograph.

10.21 Leakage Current Test (*see* Note under 10.20.1)

10.21.1 *Enclosure Leakage Current (Between Mains Supply and External Parts)* —The equipment shall be connected in the manner shown in Fig. 6 whereby the active and neutral supply conductors may be transposed. Any earthing conductor to the equipment shall be disconnected and the equipment shall be mounted so as to be isolated from earth. The neutral conductor of the test circuit shall be connected to earth. The equipment shall be operated until maximum operating temperature is reached.

10.21.1.1 The leakage current shall be measured with the supply conductors connected normally and then with the supply conductors

reversed. When taking each measurement, the controls of the equipment shall be adjusted over the complete range liable to be used in normal practice.

10.21.1.2 The leakage current shall be measured between earth and external metal parts of the electrocardiograph of metal foil arranged in intimate contact with external insulating parts. Measurements shall be made with an instrument capable of clearly indicating 100 μA. The leakage current so measured shall not exceed an instantaneous value of 100 μA.

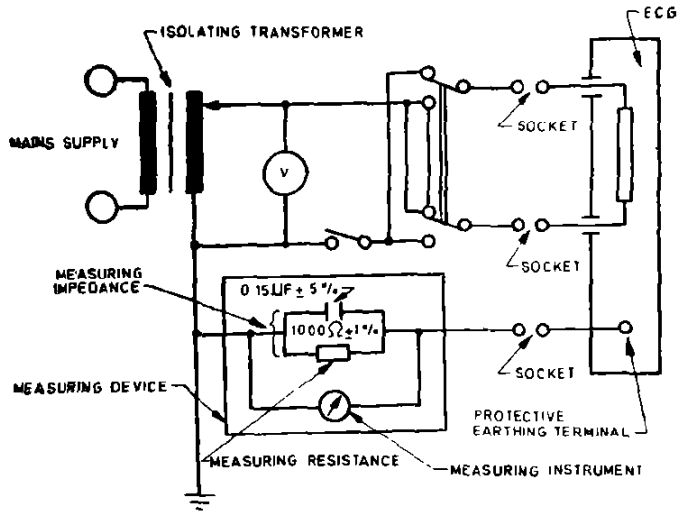
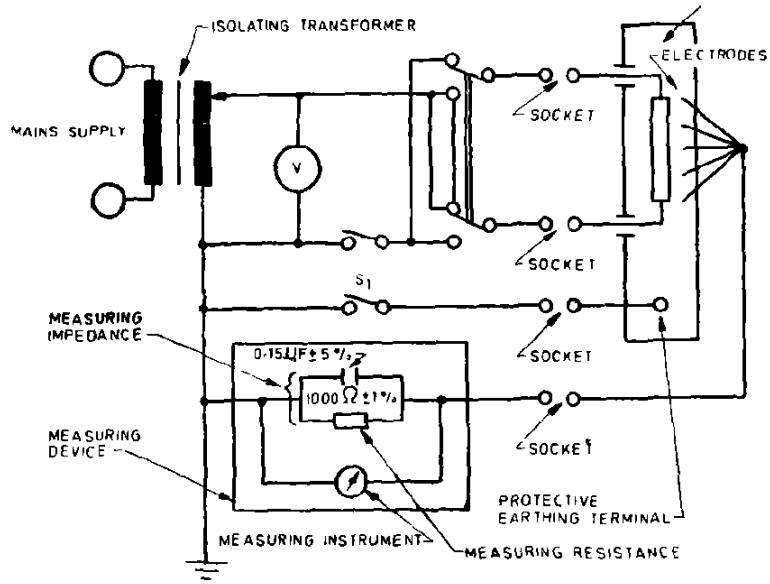


FIG. 6 MEASURING CIRCUIT FOR TESTING LEAKAGE CURRENT BETWEEN MAINS SUPPLY AND EXTERNAL PARTS

10.21.2 *Patient Leakage Current (Between Mains Supply and Patient Circuit)* — The equipment shall be connected in the manner shown in Fig. 7 whereby the active and neutral supply conductors may be transposed, and all patient electrodes are connected together and to the earth pin of the mains connecting plug. Any earthing conductors to the equipment shall remain connected but the equipment shall be mounted so that its case is isolated from the earth. The equipment shall be operated until maximum operating temperature is reached.

10.21.2.1 Patient leakage current between all electrodes connected together and the earth shall not exceed 100 μA.



NOTE — Measurement is to be made with switch S_1 closed.

FIG. 7 MEASURING CIRCUIT FOR TESTING LEAKAGE CURRENT BETWEEN MAINS SUPPLY AND PATIENT CIRCUIT

10.21.3 *Patient Leakage Current (Between Enclosure and Patient Circuit)* — The equipment shall be connected in the manner shown in Fig. 8 whereby voltage of 30 V is applied to enclosure and the current between the enclosure and all the electrodes connected together is measured. This leakage current shall not exceed 100 μA *(This test is under review)*.

10.22 Interlead and Input Impedance

10.22.1 *Interlead Impedance* — A peak-to-peak sinusoidal signal of 1 mV at a frequeucy of 200 Hz is applied to each electrode in turn, all unused electrodes being connected together (*see* Fig. 9).

10.22.1.1 A resistor (300 kΩ) is connected in series with a generator. The input signal is first applied with the resistor at zero (switch *S* closed) and the peak-to-peak output from electrocardiograph amplifier is monitored by means of an oscilloscope. Then the resistor is connected into the input circuit (switch *S* open). The output amplitude shall not be less than half amplitude of the original value when switch *S* is closed.

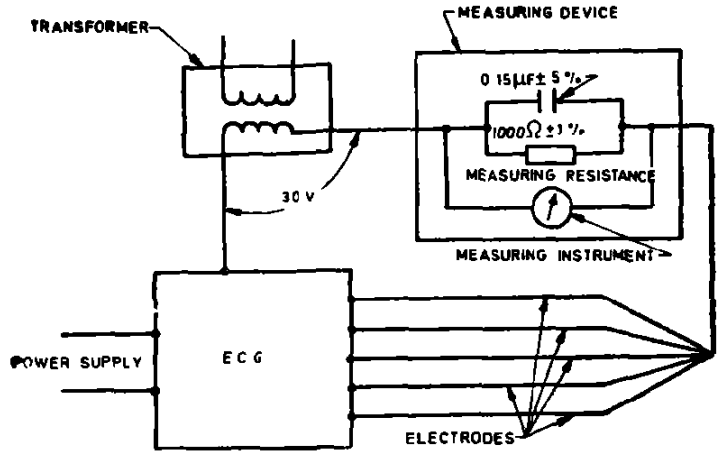


FIG. 8 MEASUREMENT OF A PATIENT LEAKAGE CURRENT BETWEEN ENCLOSURE AND PATIENT CIRCUIT

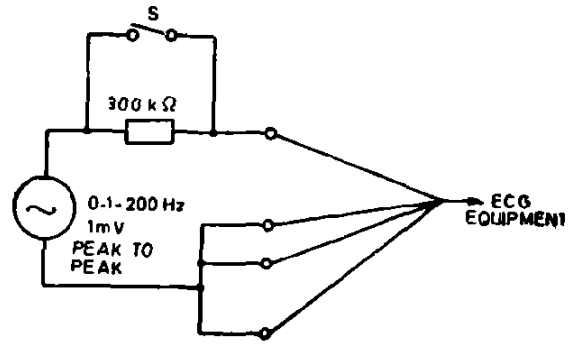


FIG. 9. MEASUREMENT OF INTERLEAD IMPEDANCE

10.22.2 *Input Impedance* — The measurement shall be carried out in accordance with Fig. 10. A peak-to-peak sinusoidal signal of 1 mV at a suitable frequency not exceeding 70 Hz shall be applied between leads *R* and *L* and the lead selector switch is kept at position 1 (*see* Fig. 4). A resistance of 2 MΩ is put in series with the generator. The input signal is first applied with resistor at zero (switch *S* closed) and the peak-to-peak output on the trace noted. Then resistor is applied into input circuit (switch *S* open). The output amplitude shall not be less than half the original value.

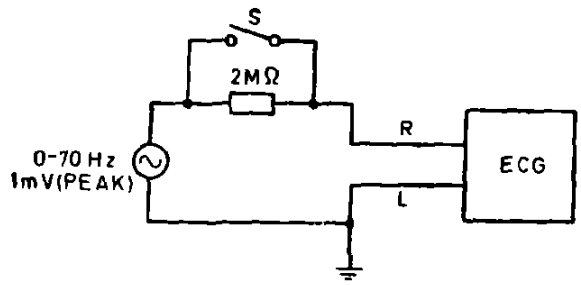


FIG. 10 MEASUREMENT OF INPUT IMPEDANCE

APPENDIX A

(*Clause* 0.3)

INFORMATIONS RELATING TO USE OF ELECTROCARDIOGRAPH

A-1. POLARITY AND IDENTIFICATION OF PATIENT LEADS

A-1.1 The polarity and identification of each type of leads shall be as follows:

Standard	I	*L*	*R*
Limb lead	II	*F*	*R*
(Einthoven)	III	*F*	*L*
Augmented	*aVR*	*R*	Central point *L* and *F*
Leads	*aVL*	*L*	Central point *R* and *F*
(Goldberger)	*aVF*	*F*	Central point *R* and *L*
Unipolar chest lead (Wilson test)	*V*	Chest	Wilson's central terminal

A-1.2 Identification of the chest positions according to Wilson is as follows:

C 1 : Fourth intercostal space at right border of sternum

C 2 : Fourth intercostal space at left border of sternum

C 3 : Fifth rib between *C* 2 and *C* 4

C 4 : Fifth intercostal space on left mid-clavicular line

C 5 : Left anterior axillary line at the horizontal level of *C* 4
C 6 : Left mid-axillary line at the horizontal level of *C* 4.
C 7 : Fifth intercostal space on the left posterior axillary line.
C 8 : Fifth intercostal space on the left mid-scapular line.

A-2. PRECAUTIONS

A-2.1 The sensitivity of the electrocardiographs specified in this standard may be such as to make the instruments unsuitable for recording electrocardiograms directly from the heart muscle.

A-2.2 Where, in special circumstances, it is required to record directly from the heart muscle for safety reasons it is essential that the right leg electrode is not brought into electrical contact with the heart muscle and that no other items of a electrical equipment are in contact with the patient.

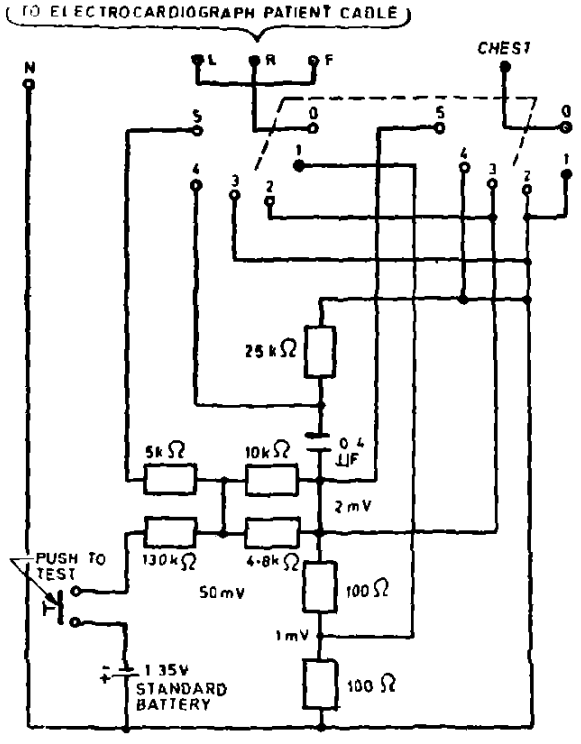
APPENDIX B

(*Clause* 0.4)

TESTING DEVICE

B-1. Since deterioration of the electrical characteristics of an electrocardiograph is not readily apparent from examination of a calibration pulse or a clinical record, a simple testing device is advocated. The testing system employs a switch, seven resistors, and a capacitor (Fig. 11). By serially advancing the switch and depressing the calibration button, the low-frequency response, linearity, high-frequency response, input impedance, and common mode rejection ratio may be evaluated. The result of each test may be read as an amplitude of deflection of the pen in accordance with Table 7. One exception is the test of low-frequency response which is evaluated in terms of the time required for a 10 mm (1 mV) signal to decay to 9 mm.

Although the foregoing system will permit regular testing to be done easily by an electrocardiographic technician, it is not intended that such test be regarded as equivalent to complete performance evaluation necessary to satisfy all recommendations in this standard.



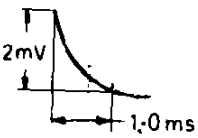
NOTE 1 — All tests to be performed with lead switch in *V* position.

NOTE 2 — All resistors are ±1 percent tolerance and capacitor is ±2 percent tolerance.

FIG 11 SUGGESTED DEVICE FOR CHECKING PERIODICALLY THE LOW- AND HIGH-FREQUENCY RESPONSE, LINEARITY, INPUT IMPEDANCE AND COMMON MODE REJECTION OF DIRECT-WRITING ELECTROCARDIOGRAPHS

TABLE 7 OPERATION OF AN INTERPRETATION OF RESULTS FROM TESTING DEVICE ILLUSTRATED IN FIGURE 10

(*Clause* B-1)

Switch Position	Test Signal	Test	Reading
(1)	(2)	(3)	(4)
0	None		
1	1 mV step to chest lead	Low-frequency response (time constant)	When the calibration button is held down and the electro-cardiograph is on 10 mm/mV sensitivity the time for the fall of magnitude (ignoring any over shoot) to the $\frac{1}{e}$ the value, that is, 37 percent should be at least 1·5 seconds
2	2 mV step to chest lead	Linearity	Upward deflection of $20 \pm 0{\cdot}5$ mm
3	2 mV step to central terminal	Linearity	Downward deflection of $20 \pm 0{\cdot}5$ mm
4		High-frequency response	Deflection should be equal to or larger than 2 mm
5	50 mV step to chest lead through to 10 kΩ resistor and to central terminal through 5 kΩ	Input impedance and common mode rejection ratio	Deflection should be less than 1 mm

APPENDIX C

(*Clause* 10.2.1)

SAMPLING PROCEDURE FOR ACCEPTANCE TESTS

C-1. LOT

C-1.1 In any consignment, all electrocardiographs of the same make, model and type and manufactured under similar conditions of production shall be grouped together to constitute a lot.

C-2. SELECTION OF SAMPLE AND CRITERION FOR CONFORMITY

C-2.1 The number of electrocardiographs, to be selected from the lot shall depend on the size of the lot.

C-2.2 For a lot size up to 25 electrocardiographs, one electrocardiograph shall be subjected to the acceptance tests. If it passes all the tests, the lot shall be considered to conform to the requirements of acceptance tests. If the sample fails in any of the acceptance tests, a further sample of 2 electrocardiographs shall be subjected to all the acceptance tests, and no failure shall occur in any of the tests.

C-2.3 For a lot size of more than 25 electrocardiographs, 2 electrocardiographs shall be subjected to the acceptance tests. If both these electrocardiographs pass all the acceptance tests the lot shall be considered to conform to the requirements of acceptance test. If both the electrocardiographs fail in any of these test the lot shall be rejected. If only one of the electrocardiographs fails in any of the acceptance tests, a further sample of 4 electrocardiographs shall be subjected to all the acceptance tests. No electrocardiograph shall fail in any of the acceptance tests.

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

Quantity	*Unit*	*Symbol*
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

Quantity	*Unit*	*Symbol*
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

Quantity	*Unit*	*Symbol*	*Definition*
Force	newton	N	1 N = 1 kg.m/s^2
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m^2
Frequency	hertz	Hz	1 Hz = 1 c/s (s^{-1})
Electric conductance	siemens	S	1 S = 1 A/V
Electromotive force	volt	V	1 V = 1 W/A
Pressure, stress	pascal	Pa	1 Pa = 1 N/m^2

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